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UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

AMARIN PHARMA, INC. and AMARIN PHARMACEUTICALS IRELAND LIMITED,

Plaintiffs,

v.

HIKMA PHARMACEUTICALS USA INC. et al.,

Defendants.

CASE NO.: 2:16-cv-02525-MMD-NJK

Consolidated with
2:16-cv-02562-MMD-NJK

DEFENDANTS' MOTION FOR SUMMARY JUDGMENT OF NONINFRINGEMENT

ORAL ARGUMENT REQUESTED

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GLOSSARY OF ABBREVIATIONS

Amarin	Plaintiffs Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Limited
ANDA	Abbreviated New Drug Application
Apo B	apolipoprotein B
Budoff	Amarin's clinical infringement expert, Matthew Budoff, M.D.
Defendants	Defendants Hikma Pharmaceuticals USA Inc., Hikma Pharmaceuticals International Limited, Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd.
DHA	docosahexaenoic acid
EPA	eicosapentaenoic acid
Ex.	exhibit attached to the Declaration of Claire A. Fundakowski
FDA	U.S. Food and Drug Administration
Peck	Amarin's FDA expert, Carl Peck, M.D.
Toth	Amarin's validity expert, Peter Toth, M.D.
LDL-C	low-density lipoprotein cholesterol

1 **I. INTRODUCTION**

2 Defendants move for summary judgment of noninfringement as to all 15 asserted patent
 3 claims from six related patents that Amarin contends cover methods of using its branded drug
 4 product, Vascepa®. Vascepa contains the active ingredient icosapent—a purified version of
 5 eicosapentaenoic acid, or “EPA,” found naturally in fish oil—and is indicated as an adjunct to
 6 diet solely to reduce very high triglyceride levels, i.e., to treat severe hypertriglyceridemia.

7 As background, Amarin did not invent purified EPA, or its use in reducing triglyceride
 8 levels. It has been known since the 1970s that diets high in fish oils—which include EPA and
 9 docosahexaenoic acid (“DHA”)—can lower triglyceride levels. Ex. 1 (Fisher Tr.) at 52:23-25.
 10 By 2004, the U.S. Food and Drug Administration (“FDA”) approved a prescription fish-oil
 11 supplement called Lovaza, an approximately 60/40 mixture of EPA and DHA, for the same
 12 indication as Vascepa—i.e., to treat severe hypertriglyceridemia. Ex. 2 (Toth Tr.) at 161:4-
 13 162:18. A pure-EPA product called Epadel has been available in Japan since the 1990s to reduce
 14 triglyceride levels. *See, e.g., id.* at 139:3-5, at 141:9-142:12. And prior-art studies used a 4g/day
 15 daily dosage of purified EPA, the same dosage in Amarin’s claims, to reduce triglycerides. *Id.* at
 16 196:6-13.

17 Amarin thus does not purport to have discovered the use of 4g/day of pure EPA to reduce
 18 triglycerides. Instead, Amarin claims to have improved this prior-art method of treatment. In
 19 addition to requiring 4g/day of purified icosapent, all 15 asserted claims also require treating a
 20 patient who has a triglyceride level of at least 500 mg/dL for a period of at least 12 weeks.
 21 Fourteen of these claims also require effects on low-density lipoprotein cholesterol (“LDL-C”), a
 22 specific percent reduction in triglycerides, effects on apolipoprotein B (“Apo B”), and/or that the
 23 patient does not concurrently receive a lipid altering therapy, e.g., a statin.

24 It is against this backdrop that Amarin sued Defendants under the Hatch-Waxman Act for
 25 filing their respective Abbreviated New Drug Applications (“ANDAs”) with the FDA seeking
 26 approval to market generic versions of Vascepa before the asserted patents expire. Because
 27 Defendants are generic drug manufacturers that do not treat any patients, Amarin does not allege
 28

1 that Defendants will directly infringe. Instead, Amarin is attempting to meet its heavy burden of
 2 holding Defendants vicariously liable for hypothetical direct infringement by doctors who will
 3 prescribe Defendants' ANDA products under theories of indirect infringement—namely, active
 4 inducement and contributory infringement, 35 U.S.C. §§ 271(b) and (c).

5 The asserted claims are all invalid as obvious. But the Court need not reach that defense
 6 because, as shown below, Amarin's theories of indirect infringement fail as a matter of law.
 7 Summary judgment should be granted on all asserted patent claims for both Defendants.

8 ***Amarin's claims for induced infringement fail as a matter of law.*** To prevail on its
 9 inducement claims, Amarin bears a far heavier burden than merely showing that doctors will
 10 directly infringe. Amarin also must prove that Defendants "have the *specific intent*, based on the
 11 contents of their proposed [drug] labels, *to encourage* physicians to use their proposed ANDA
 12 products to" practice the claimed methods. *Grunenthal GMBH v. Alkem Labs. Ltd.*, 919 F.3d
 13 1333, 1339 (Fed. Cir. 2019) (emphasis added). Because induced infringement in this context
 14 turns on the undisputed product labeling, courts routinely address (and reject) inducement claims
 15 in pre-trial motions. *See note 17, infra.* Amarin's inducement claims likewise fail as a matter of
 16 law.

17 Critically, under controlling Federal Circuit precedent, a drug-product label does not
 18 necessarily induce infringement even if the FDA-approved indication is broad enough to cover
 19 the patented method within its scope. Instead, that label must "specifically encourage" the
 20 patented method, *id.*—otherwise, any direct infringement has not been "*actively induce[d]*," 35
 21 U.S.C. § 271(b) (emphasis added). Thus, "[t]he question is not just whether instructions
 22 describ[e] the infringing mode, but whether the instructions teach an infringing use of the device
 23 *such that* we are willing to infer from those instructions an affirmative intent to infringe the
 24 patent." *Takeda Pharm. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir.
 25 2015) (quotation omitted; emphasis in original).

26 This Court should reject all inducement contentions here for one simple reason:
 27 Defendants' "labels do not specifically encourage" using the drug for at least 12 weeks—a
 28

1 limitation of every asserted claim. *Grunenthal*, 919 F.3d at 1339. The Dosage and
 2 Administration section of Defendants' product labels, which mirror the Vascepa label as required
 3 by FDA regulations, is silent as to treatment duration. Instead, as Amarin's own experts
 4 concede, the labels "leave[] it up to the discretion of the doctor to determine the duration of
 5 treatment"—which can include either short-term (i.e., less than 12 weeks) or long-term (at least
 6 12 weeks) treatment. Ex. 3 (Peck Tr.) at 141:25-142:3, 144:13-22; Ex. 4 (Budoff Tr.) at 199:9-
 7 14 (same). The labels thus specifically encourage no treatment duration, much less the patented
 8 long-term use.

9 Amarin nonetheless argues that inducement here should be inferred, but that theory
 10 conflicts with precedent. The accused labels mention a 12-week treatment duration only once,
 11 when simply describing the results of a 12-week clinical study. According to Amarin's experts,
 12 this mere clinical-trial description "*implicitly*" encourages using the drug for 12 weeks or longer.
 13 Ex. 3 (Peck Tr.) at 142:4-7. Not so. The Federal Circuit has been very clear that merely
 14 describing the patented mode is insufficient—as a matter of law—to meet the strict inducement
 15 standard. Again, "[t]he question is not just whether instructions *describ[e]* the infringing mode,"
 16 *Takeda*, 785 F.3d at 631, but whether the labeling instructions "specifically encourage" the
 17 patented method, *Grunenthal*, 919 F.3d at 1339. "'It is not enough that a user following the
 18 instructions may end up practicing the patented method.'" *In re Depomed Patent Litig.*, No. 13-
 19 4057(CCC-MF), 2016 WL 7163647, at *58 (D.N.J. Sept. 30, 2016), *aff'd sub nom. Grunenthal*,
 20 919 F.3d 1333 (Fed. Cir. 2019). "At most, [Defendants' labels] may be understood to permit an
 21 infringing use [for 12 weeks], but permission is different from encouragement." *Shire LLC v.*
 22 *Amneal Pharm., LLC*, No. 11-3781(SRC), 2014 WL 2861430, at *5 (D.N.J. June 23, 2014)
 23 (partial summary judgment of noninfringement), *aff'd in part, rev'd in part on other grounds*,
 24 802 F.3d 1301 (Fed. Cir. 2015). Because Defendants' proposed labels, on their face, are
 25 "indifferent to which [duration] is selected" by the treating physician, Amarin has "failed to raise
 26 a material factual dispute over whether the proposed label[s] encourage[] infringement" and give
 27 rise to an inference of specific intent to cause that result. *Id.*

1 Amarin’s failure to show that Defendants’ labels induce—i.e., specifically encourage—
 2 use of the drug for at least 12 weeks is sufficient to reject all inducement theories in this case.
 3 But independently, Amarin also cannot prove inducement for the 14 (out of 15) asserted claims
 4 that require clinical effects beyond a general reduction in triglycerides, the only FDA-approved
 5 use of icosapent. These claims require administering icosapent, for example: (1) to control blood
 6 lipid levels other than triglycerides, such as LDL-C and Apo B; (2) to reduce triglycerides by
 7 specific amounts (e.g., by 25%); and/or (3) to exclude co-administration with a statin or other
 8 lipid-altering therapy. Nothing in Defendants’ labels induces—i.e., specifically encourages—
 9 any of these patented uses.

10 In addition to there being no specific encouragement, Amarin legally cannot show that
 11 Defendants induce infringement of the 14 claims requiring controlling LDL-C or Apo B because
 12 these uses are not FDA-approved. The law is clear that, in the Hatch-Waxman context for
 13 method-of-use patents such as the ones at issue in this case, “the ‘artificial’ infringement claim
 14 provided by section 271(e)(2)(A) lies only against a patented use that has been approved by the
 15 FDA.” *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1319 (Fed. Cir. 2012) (citing
 16 *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1355-56 (Fed. Cir. 2003)). Amarin’s
 17 experts expressly admit that Vascepa [REDACTED]

18 [REDACTED] Ex. 4 (Budoff Tr.) at 180:22-24, 181:6-8. Because the FDA has not approved
 19 Vascepa for controlling LDL-C or Apo B, Defendants cannot, as a matter of law, induce
 20 infringement of these patent claims for this independent reason.

21 ***Amarin’s contributory infringement claims fail as a matter of law.*** As to contributory
 22 infringement, the statute itself requires Amarin to prove that Defendants’ products are
 23 “especially made or especially adapted for use in an infringement of [its] patent[s], and not . . .
 24 suitable for substantial noninfringing use.” 35 U.S.C. § 271(c). “Unless a [product] has *no use*
 25 except through practice of the patented method, the patentee has no right to claim that its
 26 distribution constitutes contributory infringement.” *Sony Corp. of Am. v. Universal City Studios*,

1 *Inc.*, 464 U.S. 417, 441 (1984) (quotation omitted; emphasis added). Amarin has no viable
 2 theory of contributory infringement.

3 As for the 12-week limitation in all 15 asserted claims, Amarin’s clinical infringement
 4 expert concedes that Defendants’ ANDA products are [REDACTED]

5 [REDACTED] Ex. 4 (Budoff Tr.)

6 at 253:12-18. Indeed, he agrees that Amarin’s own clinical study on Vascepa (the MARINE
 7 study), portions of which are summarized in the Vascepa label, [REDACTED]

8 [REDACTED] *Id.* at 252:19-22. Amarin’s own patents
 9 admit that icosapent is effective for its approved use of reducing triglycerides in as little as “1
 10 week.” *See, e.g.*, Ex. 5, U.S. Patent No. 8,293,728 (“the ’728 patent”) at 3:65-4:7.¹ These
 11 undisputed facts, alone, are sufficient to defeat Amarin’s contributory infringement theories.

12 As for the 14 asserted claims that require additional limitations, Amarin’s MARINE
 13 study reports that [REDACTED]

14 [REDACTED]. Amarin’s
 15 experts concede these undisputed facts, *infra* pages 6-7, which also show substantial
 16 noninfringing uses.

17 As for the four asserted claims that exclude a concurrent lipid altering therapy, 25% of
 18 patients in Amarin’s MARINE study were co-administered a concurrent lipid altering therapy in
 19 the form of a statin. Amarin’s clinical infringement expert admits that [REDACTED]

20 [REDACTED], thus showing a
 21 substantial noninfringing use. *See* Ex. 4 (Budoff Tr.) at 171:9-172:11.

22 In sum, there is no genuine dispute as to any material fact regarding induced or
 23 contributory infringement for any asserted claim, and summary judgment should be granted.

24
 25
 26
 27 ¹ Since all six patents-in-suit are related, their disclosures—the information contained in their
 28 respective specifications—are essentially the same.

1 **II. CONCISE STATEMENT OF UNDISPUTED MATERIAL FACTS**

2 This motion turns on a discrete number of uncontested, material facts from just three sets
 3 of documents. Amarin’s own experts concede that these material facts are all undisputed.

4 1. According to Amarin’s own patents:

- 5 a. Each of the 15 asserted claims requires administering icosapent to a
 patient for at least “12 weeks”²;
- 6 b. Fourteen of those claims further require at least one of the following
 effects: (i) a reduction in triglycerides that is “statistically significant” or
 “of at least about” 10%, 20%, or 25%³; (ii) no increase, no “substantial[]”
 increase, no “statistically significant” increase, or no “more than 5%”
 increase in LDL-C levels⁴; or (iii) a reduction in “apolipoprotein B”⁵;
- 12 c. Four asserted claims require that the patient “not receive concurrent lipid
 altering therapy,” e.g., a statin⁶; and
- 13 d. Patients can “exhibit[]” the “outcome[]” of “reduced triglyceride levels
 compared to baseline” in as few as “about 1” to “about 10 weeks,” i.e., in
 less than 12 weeks.⁷

17

18 ² Ex. 5, ’728 pat., Claims 1, 13, and 16; Ex. 6, U.S. Patent No. 8,318,715 (“the ’715 patent”),
 19 Claim 14; Ex. 7, U.S. Patent No. 8,357,677 (“the ’677 patent”), Claims 1, 7, and 8; Ex. 8, U.S.
 20 Patent No. 8,367,652 (“the ’652 patent”), Claims 1, 7, and 8; Ex. 9, U.S. Patent No. 8,431,560
 21 (“the ’560 patent”), Claims 4, 7, and 17; Ex. 10, U.S. Patent No. 8,518,929 (“the ’929 patent”),
 22 Claims 1 and 5.

23

24 ³ Ex. 5, ’728 pat., Claim 13; Ex. 6, ’715 pat., Claim 14; Ex. 7, ’677 pat., Claim 7; Ex. 8, ’652
 25 pat., Claim 7; Ex. 9, ’560 pat., Claims 4, 7, and 17.

26

27 ⁴ Ex. 5, ’728 pat., Claims 1, 13, and 16; Ex. 6, ’715 pat., Claim 14; Ex. 7, ’677 pat., Claims 1, 7,
 28 and 8; Ex. 8, ’652 pat., Claims 1, 7, and 8; Ex. 9, ’560 pat., Claims 4, 7, and 17.

29

30 ⁵ Ex. 6, ’715 pat., Claim 14; Ex. 7, ’677 pat., Claim 8; Ex. 8, ’652 pat., Claim 8; Ex. 10, ’929
 31 pat., Claim 5.

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33 ⁶ Ex. 5, ’728 pat., Claims 1, 13, and 16; Ex. 6, ’715 pat., Claim 14.

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35 ⁷ Ex. 5, ’728 pat. 3:65-4:7; *see also id.* at 4:62-5:15, 7:54-8:2; Ex. 6, ’715 pat. 3:65-4:7, 4:62-
 36 5:15, 7:54-8:2; Ex. 7, ’677 pat. 4:1-4:10, 4:65-5:18, 7:58-8:6; Ex. 8, ’652 pat. 4:1-4:10, 4:65-
 37 5:18, 7:58-8:6; Ex. 9, ’560 pat. 4:1-4:10, 4:65-5:18, 7:58-8:6; Ex. 10, ’929 pat. 4:1-4:10, 4:65-
 38 5:18, 7:58-8:6.

1 2. Amarin's own MARINE study reports, among other things, that:

2 a. Icosapent is effective for reducing triglycerides in just four weeks⁸;

3 b. About 21% of patients kept triglyceride levels from becoming "very high"

4 with diet and exercise alone⁹;

5 c. [REDACTED]

6 [REDACTED]¹⁰;

7 d. [REDACTED] [REDACTED]¹¹;

8 e. [REDACTED] [REDACTED]¹²; and

9 f. About 25% of patients concurrently received a statin while on Vascepa

10 therapy.¹³

11 3. Defendants' proposed product labels:

12 a. Are indicated solely "as an adjunct to diet to reduce triglyceride (TG)

13 levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia"¹⁴;

14 b. Have [REDACTED]¹⁵;

15 and

16

17 ⁸ Ex. 11 (FDA Medical Review for Vascepa) at 50-51, 53-54, 67-68; Ex. 12 (MARINE study report) at 73; Ex. 4 (Budoff Tr.) at 252:19-22.

18

19 ⁹ Ex. 11 (FDA Medical Review for Vascepa) at 50; Ex. 12 (MARINE study report) at 72; Ex. 4 (Budoff Tr.) at 92:11-93:3.

20 ¹⁰ Ex. 12 (MARINE study report) at 71; *see id.* at AMRN00053668; *accord* Ex. 4 (Budoff Tr.) at 110:6-13, 110:24-111:5.

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22 ¹¹ Ex. 12 (MARINE study report) at 82; *see id.* at AMRN00053724; Ex. 2 (Toth Tr.) at 271:16-19; Ex. 4 (Budoff Tr.) at 248:3-23.

23

24 ¹² Ex. 12 (MARINE study report) at 79; *see id.* at AMRN00053695; Ex. 2 (Toth Tr.) at 318:4-9; Ex. 4 (Budoff Tr.) at 244:9-19.

25

26 ¹³ Ex. 12 (MARINE study report) at 69; Ex. 3 (Peck Tr.) at 103:6-11; Ex. 4 (Budoff Tr.) at 211:11-16.

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28 ¹⁴ Ex. 13 (Vascepa label) at 1-2; Ex. 14 (Hikma label) at 1; Ex. 15 (DRL label) at 1-2; Ex. 16 (FDA Complete Response Letter) at 1 (rejecting indications for Vascepa to control LDL-C and Apo B levels).

15 Ex. 4 (Budoff Tr.) at 198:19-23.

c. Describe administering Vascepa to patients concurrently receiving a statin.¹⁶

III. ARGUMENT

Summary judgment should be granted because “there is no genuine dispute as to any material fact and [Defendants are] entitled to judgment as a matter of law” on the 15 asserted method claims. Fed. R. Civ. P. 56(a). “A method claim is directly infringed only by one practicing the patented method.” *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 775 (Fed. Cir. 1993). As noted, Amarin does not contend that Defendants—generic drug manufacturers that do not treat patients—“will ever practice any of the methods claimed.” *Warner-Lambert Co.*, 316 F.3d at 1363. Amarin alleges only that Defendants will indirectly infringe the asserted patents under 35 U.S.C. §§ 271(b) and (c) by inducing or contributing to direct infringement.

Because Defendants have not yet launched their generic products, Amarin brought its infringement claims under the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2)(A), which “provides an ‘artificial’ act of infringement that creates case-or-controversy jurisdiction to enable the resolution of an infringement dispute before the ANDA applicant has actually made or marketed the proposed product.” *Warner-Lambert Co.*, 316 F.3d at 1365. “Once jurisdiction is established, however, the substantive determination whether actual infringement or inducement will take place is determined by traditional patent infringement analysis, just the same as it is in other infringement suits.” *Id.* Amarin’s infringement claims thus turn on whether Defendants will induce infringement under § 271(b) or contribute to infringement under § 271(c)—issues that courts routinely decide as a matter of law, including on summary judgment. *See, e.g., id.* at 1366 (affirming summary judgment of no inducement); *Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1363 (Fed. Cir. 2012) (affirming summary judgment of no contributory infringement); *see also* note 17, *infra*.

As discussed below, Amarin cannot meet its burden of proving indirect infringement for three independent, legal reasons. First, the labels for Defendants' ANDA products do not

¹⁶ Ex. 13 (Vascepa label) at 5-7; Ex. 14 (Hikma label) at 5-6; Ex. 15 (DRL label) at 6-8.

1 encourage administering icosapent for 12 weeks, as required by all 15 asserted claims, and the
2 products themselves are suitable for the substantial noninfringing use of reducing a patient's
3 triglycerides in less than 12 weeks. *Infra*, Part A. Second, as to the 14 claims that require
4 specific effects on a patient's blood lipid levels, Defendants' labels do not encourage using their
5 products to achieve the claimed effects, and the products are suitable for the substantial
6 noninfringing use of reducing a patient's triglycerides without achieving those effects. *Infra*,
7 Part B. Third, for the four claims that exclude administration of icosapent with a concurrent
8 lipid-altering therapy, Defendants' labels do not encourage using their products in that manner,
9 and the products are suitable for the substantial noninfringing use of reducing a patient's
10 triglycerides with a concurrent lipid-altering therapy. *Infra*, Part C.

11 Summary judgment of noninfringement is thus warranted.

12 **A. Amarin cannot prove indirect infringement of any asserted claim.**

13 Every asserted claim requires administering icosapent to a patient for at least 12 weeks.
14 Even assuming that physicians will prescribe Defendants' products for that duration and directly
15 infringe, Amarin cannot establish that Defendants will induce or contribute to such infringement.
16 For this reason alone, Amarin's claims for indirect infringement fail as a matter of law.

17 **1. Defendants cannot induce infringement of any asserted claim because
18 their labels do not encourage administering icosapent for 12 weeks.**

19 While Congress holds direct infringers strictly liable, inducement liability under the
20 Patent Act attaches only to one who "actively induces infringement." 35 U.S.C. § 271(b)
21 (emphasis added). Thus, "[t]he mere existence of direct infringement by physicians, while
22 necessary to find liability for induced infringement, is not sufficient for inducement." *Takeda*,
23 785 F.3d at 631. Active "inducement requires that the alleged infringer knowingly induced
24 infringement and possessed specific intent to encourage another's infringement." *DSU Med.*
25 *Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (en banc) (internal quotation omitted).
26 "The intent requirement for inducement requires more than just intent to cause the acts that
27 produce direct infringement"—"the inducer must have an affirmative intent to cause direct

1 infringement.” *Id.* It follows that proof of “inducement requires evidence of culpable conduct,
 2 directed to encouraging another’s infringement, not merely that the inducer had knowledge of the
 3 direct infringer’s activities.” *Id.* (citation omitted).

4 In the ANDA context, “the question of induced infringement turns on whether
 5 [Defendants] have the specific intent, based on the contents of their proposed labels, to
 6 encourage physicians to use their proposed ANDA products to” practice the claimed methods.
 7 *Grunenthal*, 919 F.3d at 1339. Where, as here, the defendants have not launched their proposed
 8 generic drug products, the inquiry turns solely on “whether the label encourages, recommends, or
 9 promotes infringement.” *Id.*¹⁷

10 Earlier this year, the Federal Circuit in *Grunenthal* confirmed that inferring specific
 11 intent from a product label presents a very high hurdle for patentees like Amarin. There, the
 12 drug product was indicated to treat severe chronic pain. Grunenthal’s patent, however, was
 13 limited to methods of treating a specific type of severe chronic pain—i.e., polyneuropathic pain.
 14 Grunenthal argued that the label would inevitably lead at least some users to infringe. But the
 15 Federal Circuit rejected that theory, holding that “even if severe chronic pain includes
 16 polyneuropathic pain, it also includes [other types of] pain. Therefore, the proposed ANDA
 17 labels do not specifically encourage use of [the drug product] for treatment of polyneuropathic
 18 pain.” *Grunenthal*, 919 F.3d at 1339 (emphasis added). The Federal Circuit thus affirmed the
 19 judgment of no induced infringement. *Id.* at 1340.

20 Consistent with *Grunenthal*, the District of New Jersey in *Shire* had granted summary
 21 judgment of noninfringement even though it was clear that at least some direct infringement

22 ¹⁷ This issue is thus suited for resolution on summary judgment, and courts routinely reject
 23 inducement claims in that context. See, e.g., *Warner-Lambert Co.*, 316 F.3d at 1366 (summary
 24 judgment of noninfringement); *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1334 (Fed.
 25 Cir. 2003) (same); *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1324-26 (Fed. Cir.
 26 2012) (judgment on the pleadings of no infringement); *AstraZeneca Pharms. LP v. Apotex Corp.*,
 27 669 F.3d 1370, 1380 (Fed. Cir. 2012) (dismissal of infringement claims on the pleadings); *Shire*,
 28 2014 WL 2861430, at *5 (partial summary judgment of noninfringement); *Allergan, Inc. v. Sandoz Inc.*, 2011 WL 3794364, at *6 (E.D. Tex. Aug. 25, 2011) (summary judgment of
 noninfringement); *ICN Pharm., Inc. v. Geneva Pharm. Tech. Corp.*, 272 F. Supp. 2d 1028, 1049
 (C.D. Cal. 2003) (same).

1 would occur. The patent claimed the use of a drug “with intake of food,” and the Dosing and
 2 Administration section of the proposed labeling instructed “that the products may be taken ‘with
 3 or without food.’” 2014 WL 2861430, at *4-5. The labeling thus plainly included the patented
 4 use, which presumably would be practiced by at least some patients. The court nonetheless
 5 entered summary judgment because the label did not specifically encourage any inevitable
 6 infringement: “The problem is that the statement that the medication may be taken with or
 7 without food cannot be reasonably understood to be an instruction to engage in an infringing use.
 8 As Defendants contend, it is indifferent to which option is selected. At most, it may be
 9 understood to permit an infringing use, but permission is different from encouragement.” *Id.* at
 10 *5.

11 *Grunenthal* and *Shire* are on point. To be sure, the permissible use of Defendants’
 12 products “includes” treatment for 12 weeks, but “the proposed ANDA labels do not *specifically*
 13 *encourage* physicians to select that duration of treatment. *Grunenthal*, 919 F.3d at 1339
 14 (emphasis added). Both the Indication as well as the Dosing and Administration sections in
 15 Defendants’ proposed labeling are silent about how long the drug should be administered as an
 16 adjunct to diet, and the labels never characterize severe hypertriglyceridemia as a chronic
 17 condition. Ex. 13 (Vascepa label) at 1-2. Amarin’s FDA expert thus concedes that the labeling
 18 “leaves it up to the discretion of the doctor to determine the duration of treatment,” and Amarin’s
 19 clinical infringement expert concedes that it is [REDACTED]

20 [REDACTED] Ex. 3 (Peck Tr.) at 141:25-142:3; Ex. 4 (Budoff
 21 Tr.) at 200:13-18. Put simply, the indication is “indifferent to which [duration] option is
 22 selected” by the treating physician. *Shire*, 2014 WL 2861430, at *5.

23 In fact, the *Shire* situation was closer to infringement than this case, because it involved a
 24 binary choice: take the drug with or without food. Here, a physician has a wide range of
 25 discretion when prescribing the drug for a particular duration, with only some choices—i.e.,
 26 durations of at least 12 weeks—infringing. “At most, [the accused labels here] may be
 27 understood to permit an infringing use, but permission is different from encouragement” and
 28

1 “fail[s] to raise a material factual dispute over whether the proposed label[s] encourage[]
 2 infringement.” *Id.*; *see also Takeda Pharm. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 188 F. Supp.
 3d 367, 377 (D. Del. 2016), *vacated on other grounds*, No. 14-1268-SLR, 2016 WL 7230504 (D.
 4 Del. Dec. 14, 2016) (a label “stating that [a drug] *can* be used for [an infringing use] is not the
 5 same as stating [how the drug] *should* be used . . .”).

6 Amarin cannot avoid summary judgment by pointing to the “Clinical Studies” section of
 7 the label, which describes a particular study in which patients were “enrolled . . . for 12 weeks.”
 8 Ex. 13 (Vascepa label) at 7.¹⁸ “Merely describing an infringing mode is not the same as
 9 recommending, encouraging, or promoting an infringing use, or suggesting that an infringing use
 10 should be performed.” *Takeda*, 785 F.3d at 631 (citations, quotation marks, and alterations
 11 omitted). “The question is not just whether instructions describe the infringing mode, but
 12 whether the instructions teach an infringing use of the device such that we are willing to infer
 13 from those instructions an affirmative intent to infringe the patent.” *Id.* (alterations and quotation
 14 omitted). Here, the labels’ passing reference to a 12-week duration is “[m]erely describing” the
 15 length of time for a single clinical trial—not specifically “suggesting that an infringing use
 16 should be performed.” *Id.*

17 That conclusion is reinforced by the fact that the 12-week duration appears only in the
 18 “Clinical Studies” section of the label, which merely describes exemplary effects of the drug, as
 19 opposed to the “Indications and Usage” or “Dosage and Administration” sections, which instruct
 20 on how to use it. As Amarin’s clinical infringement expert admits, while [REDACTED]
 21 [REDACTED]

22 [REDACTED] Ex. 4 (Budoff Tr.) at 147:12-17. Indeed, “courts have repeatedly found incidental
 23 references to even infringing uses” in the descriptive sections of a label “insufficient to constitute
 24 instruction or encouragement, as opposed to mere permission.” *Otsuka Pharm. Co. v. Torrent*
 25 *Pharm. Ltd.*, 99 F. Supp. 3d 461, 490 (D.N.J. 2015) (finding that language in the

26
 27 ¹⁸ Because Defendants’ labels are materially identical to the Vascepa label, this brief cites the
 28 Vascepa label.

1 contraindications and adverse effects sections of the generic defendants' proposed labels was
 2 insufficient to induce infringement). While such sections provide information about the drug's
 3 safety and potential effects, "the weight of authority has deemed warning and safety information
 4 insufficient to constitute inducement, requiring instead that the information be set forth in the
 5 'Uses and Indication' or 'Dosing and Administration' sections." *Id.* at 493.

6 Nor can Amarin avoid summary judgment based on expert testimony about how
 7 physicians use icosapent in practice. "Information outside the label (e.g., a physician's
 8 knowledge) is not sufficient" to show inducement, because "[i]n determining whether
 9 Defendants possess the requisite specific intent, it is the . . . instructions in the label itself[] that
 10 must be evaluated." *In re Depomed*, 2016 WL 7163647, at *58, aff'd sub nom. *Grunenthal*, 919
 11 F.3d 1333. Amarin would not be the first to argue that focusing on "generic labeling ignore[s]
 12 market realities," but the Federal Circuit has found such arguments "unpersuasive." *AstraZeneca*
 13 *Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1380 (Fed. Cir. 2012) (affirming Rule 12(b)(6)
 14 dismissal of inducement claims). And "[v]ague label language cannot be combined with
 15 speculation about how physicians may act to find inducement." *Takeda*, 785 F.3d at 632. Thus,
 16 "[s]peculation or even proof that some, or even many, doctors would prescribe [Defendants'
 17 ANDA products] for [12 weeks] is hardly evidence of" inducement. *Id.* at 633. That is,
 18 "statements of [an] expert" cannot "get around the simple fact that the proposed label does not
 19 contain any instruction to" practice the claimed method. *Shire*, 2014 WL 2861430, at *5; see
 20 also *Bayer*, 676 F.3d at 1325-26 (entering judgment on the pleadings despite expert declarations,
 21 because the opinions were "contrary to the contents of the FDA-approved label").

22 The authority discussed above emphasizes the critical distinction between proof of direct
 23 infringement, where strict liability is imposed, and induced infringement, which requires both
 24 specific intent and affirmative steps to induce infringement. "If some physicians nonetheless
 25 choose to prescribe" Defendants' ANDA products for 12 weeks, "they will do so based on their
 26 own independent belief that [this] provides a benefit for their patients. [The] label does not
 27 instruct them to do so. It is not enough that a user following the instructions may end up

1 practicing the patented method.” *United Therapeutics Corp. v. Sandoz, Inc.*, Nos. 12-cv-01617,
 2 13-cv-316, 2014 WL 4259153, at *21 (D.N.J. Aug. 29, 2014). Indeed, whether “a physician,
 3 without inducement by [Defendants], prescribes a use of [icosapent] in an infringing manner . . .
 4 is legally irrelevant [to inducement]. In the absence of any evidence that [Defendants] ha[ve] or
 5 will promote or encourage doctors to infringe the [asserted] method patent[s], there has been
 6 raised no genuine issue of material fact.” *Warner-Lambert*, 316 F.3d at 1364.

7 Amarin’s claims for induced infringement as to all asserted claims in all 15 asserted
 8 patents thus fail as a matter of law for this reason alone.

9 **2. Defendants cannot contribute to infringement of any asserted claim
 10 because their products are suitable to be used for less than 12 weeks.**

11 Amarin’s contributory infringement claims also fail. The Patent Act limits contributory
 12 infringement liability to one who markets a product “knowing the same to be especially made or
 13 especially adapted for use in an infringement of such patent, and not . . . suitable for substantial
 14 noninfringing use.” 35 U.S.C. § 271(c). The patentee “ha[s] the burden to prove the lack of
 15 substantial noninfringing uses,” *Toshiba*, 681 F.3d at 1363, which include “any use that is not
 16 unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental.” *In re Bill of
 17 Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1337 (Fed. Cir. 2012)
 18 (quotation omitted). The only particular requirement “[i]n a pharmaceutical case[] [is that] the
 19 noninfringing use must be in accordance with the use for which the product is indicated.”
 20 *Grunenthal*, 919 F.3d at 1340.

21 The Supreme Court has repeatedly emphasized the intentionally limited reach of the
 22 contributory-infringement statute. The “Court has always recognized the critical importance of
 23 not allowing the patentee to extend his monopoly beyond the limits of his specific grant,” and its
 24 “cases deny the patentee any right to control the distribution of unpatented articles unless they
 25 are ‘unsuited for any commercial noninfringing use.’ *Unless a commodity ‘has no use except
 26 through practice of the patented method,’ the patentee has no right to claim that its distribution
 27 constitutes contributory infringement.”* *Sony*, 464 U.S. at 441 (quoting *Dawson Chem. Co. v.*
 28

1 *Rohm & Hass Co.*, 448 U.S. 176, 198 (1980)) (emphasis added). “To form the basis for
 2 contributory infringement the item must almost be uniquely suited as a component of the
 3 patented invention.” *Id.* (quotation omitted). The “sale of an article which though adapted to an
 4 infringing use is also adapted to other and lawful uses, is not enough to make the seller a
 5 contributory infringer.” *Id.* (quotation omitted).

6 Here, on the undisputed record, Amarin cannot meet its heavy burden under § 271(c) of
 7 showing that Defendants’ products have “no use except through practice of the patented
 8 method.” *Sony*, 464 U.S. at 441. Both the asserted patents themselves and the Amarin-
 9 sponsored MARINE clinical study that the FDA relied on to approve Vascepa confirm that
 10 Defendants’ products are not “especially made” to be used for 12 weeks. Instead, as Amarin’s
 11 experts concede, the products are approved for reducing, and thus [REDACTED]

12 [REDACTED]
 13 [REDACTED]—a substantial noninfringing use. Ex. 4 (Budoff Tr.) at 253:3-18; Ex. 3 (Peck Tr.) at
 14 144:13-22.¹⁹

15 First, the asserted patents themselves repeatedly admit that icosapent achieves “a
 16 reduction in triglyceride level” when administered to a patient for less than 12 weeks—including
 17 exemplary treatment durations of “about 1 to about 10 weeks, about 1 to about 5 weeks, about 1
 18 to about 2 weeks or about 1 week.” *See, e.g.*, Ex. 5, ’728 pat. 3:65-4:7; *see also id.* at 4:62-5:15,
 19 7:54-8:2. As exemplary durations admitted on the face of Amarin’s patents, Amarin cannot rely
 20 on expert testimony to contend that they are “unusual, farfetched, illusory, impractical,
 21 occasional, aberrant, or experimental.” *In re Bill of Lading*, 681 F.3d at 1337; *see also Smith &*

22 *Nephew, Inc. v. Rea*, 721 F.3d 1371, 1380 n.6 (Fed. Cir. 2013) (“Expert opinions that are
 23 contrary to admissions in the [patent] specification do not create a factual issue.”).

24 Nor can Amarin deny that Defendants’ ANDA products are suitable for such short-term
 25 treatment. Again, they are generally “indicated as an adjunct to diet to reduce triglyceride (TG)

26 ¹⁹ Unlike with induced infringement, information outside of the product label can be relevant to
 27 contributory infringement to show substantial noninfringing use. *See In re Depomed*, 2016 WL
 28 7163647, at *67-69.

1 levels”—without any minimum duration of treatment, which Amarin’s FDA expert agrees is
 2 entirely “up to the discretion of the doctor.” Ex. 13 (Vascepa label) at 2; 3 (Peck Tr.) at 141:25-
 3 142:3; *accord* Ex. 4 (Budoff Tr.) at 199:9-14. As Amarin’s clinical infringement expert
 4 concedes, the products are [REDACTED]

5 [REDACTED] Ex. 4 (Budoff Tr.) at 253:12-18. Because using
 6 Defendants’ ANDA products for less than 12 weeks is “in accordance with the use for which the
 7 product[s] [are] indicated,” that suitable, noninfringing use defeats Amarin’s claims of
 8 contributory infringement. *Grunenthal*, 919 F.3d at 1340.

9 Second, uncontested real-world data in Amarin’s MARINE study on Vascepa
 10 confirms that Defendants’ ANDA products are suitable to be used for less than 12 weeks.
 11 Although the MARINE study (summarized in the Vascepa label) lasted 12 weeks, Amarin’s
 12 clinical infringement expert agrees that the study [REDACTED]

13 [REDACTED] Ex. 4 (Budoff Tr.) at 252:19-22. Likewise, the
 14 FDA’s review of MARINE confirmed that “the maximum TG-lowering effect of 4 g Vascepa
 15 occurred by Week 4.” Ex. 11 (Vascepa Medical Review) at 67. About 21% of patients in the
 16 MARINE study were able to maintain levels below 500 mg/dL with diet and exercise alone.²⁰
 17 *Id.* at 50; Ex. 12 (MARINE study report) at 72.

18 Amarin’s clinical infringement expert testified that the results of MARINE were
 19 [REDACTED]
 20 [REDACTED]

21 [REDACTED] Ex. 4 (Budoff Tr.) at 93:10-16. Thus, some patients can take icosapent as
 22 an adjunct to diet and exercise for less than 12 weeks to reduce triglyceride levels below 500
 23 mg/dL and then rely solely on diet and exercise to maintain levels below that threshold. As
 24 Amarin’s expert explains, he sees [REDACTED]
 25 [REDACTED]

26
 27 ²⁰ A triglyceride level of at least 500 mg/dL is a marker for increased risk of acute pancreatitis.
 28 *See, e.g.*, Ex. 4 (Budoff Tr.) at 66:5-9; *id.* at 65:18-23, 75:17-76:3.

1 [REDACTED] *Id.* at 94:5-95:10. That is, some
 2 patients [REDACTED]

3 [REDACTED] *Id.* at 96:3-24; *see also* 97:23-98:9. In short, Amarin’s own data confirms that
 4 Defendants’ generic-Vascepa products are suitable for the substantial noninfringing use of
 5 reducing triglycerides, as an adjunct to diet, in less than 12 weeks.

6 Amarin’s own patents and clinical trial refute the notion that Defendants’ products have
 7 “no use except through practice of the patented method.” *Sony*, 464 U.S. at 442. Even assuming
 8 that Defendants’ products are “adapted to an infringing use,” they are “also adapted to other and
 9 lawful uses”—namely, reducing a patient’s triglycerides as an adjunct to diet in less than 12
 10 weeks. *Id.* Therefore, the mere fact that doctors may prescribe Defendants’ products for longer
 11 periods of time “is not enough to make [Defendants] contributory infringer[s]” as a matter of
 12 law. *Id.*

13 Given these legal principles, Amarin cannot avoid summary judgment by attempting to
 14 create a factual dispute over the actual incidence of short-term use versus long-term use of
 15 icosapent. As the Federal Circuit has held, “the frequency of infringing use . . . does not speak to
 16 the substantiality of the noninfringing use.” *Vita-Mix v. Basic Holding, Inc.*, 581 F.3d 1317,
 17 1327 (Fed. Cir. 2009) (affirming summary judgment of no infringement). In determining
 18 whether a noninfringing use is substantial, “[t]he focus is not the utility or ubiquity of the
 19 infringing configuration.” *Id.* (quotation omitted). Even if “practicing the patented method may
 20 be the most logical or useful purpose for [the accused] products[,] [that] does not render the
 21 alternative uses” insubstantial. *Bill of Lading*, 681 F.3d at 1338 (affirming dismissal of
 22 contributory infringement claim). The statute, after all, requires only that a product be “suitable
 23 for substantial noninfringing use.” 35 U.S.C. § 271(c) (emphasis added); *see also Sony*, 464 U.S.
 24 at 442 (holding in the analogous copyright context that a product “need merely be capable of
 25 substantial noninfringing use” to avoid contributory infringement) (emphasis added); *Toshiba*,
 26 681 F.3d at 1363 (affirming summary judgment of no contributory infringement, finding
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1 noninfringing use substantial even though it was not recommended, which “does not mean the
 2 non-recommended use is not substantial”).

3 Even considering the incidence of noninfringing use, Amarin’s clinical infringement
 4 expert admits that about [REDACTED] Ex.
 5 4 (Budoff Tr.) at 112:2-5. Courts have found similar estimates sufficient to defeat a claim of
 6 contributory infringement. *See In re Depomed*, 2016 WL 7163647, at *69, *aff’d sub nom.*
 7 *Grunenthal*, 919 F.3d 1333 (finding “a substantial noninfringing use” of a drug where patentee’s
 8 expert provided “estimates of less than 5%” for incidence of noninfringing use); *see also Sony*,
 9 464 U.S. at 424, 444 (finding “7.3% of all Betamax use” was a “significant quantity” of
 10 noninfringing use).

11 Because there is no genuine dispute that Defendants’ ANDA products are at least suitable
 12 for the substantial noninfringing use of reducing triglycerides in less than 12 weeks, Amarin’s
 13 claims for contributory infringement fail as a matter of law as to all asserted claims.

14 **B. Amarin cannot prove indirect infringement of the 14 asserted claims that
 15 require clinical effects other than a general reduction in triglycerides.**

16 Regardless of how the Court rules with regard to the 12-week limitation discussed above,
 17 Defendants are entitled to partial summary judgment on 14 of the 15 asserted claims for
 18 independent reasons. In addition to requiring a physician to administer icosapent for 12 weeks,
 19 all but one of the asserted claims require particular effects on certain blood lipid levels.
 20 Specifically, 14 asserted claims require one or more of the following: (1) achieving a certain
 21 minimum amount or degree of reduction in triglyceride levels; (2) not materially increasing
 22 LDL-C levels; or (3) reducing Apo B levels. As discussed below, Amarin cannot prove indirect
 23 infringement of these claims for the independent reason that Defendants will neither induce nor
 24 contribute to physicians prescribing icosapent to achieve the claimed clinical effects.

1 **1. Defendants cannot induce infringement of claims that require specific
2 effects on a patient's blood lipid levels because the labels do not
3 encourage use of icosapent to achieve those effects.**

4 As a matter of law, Amarin cannot prove induced infringement of the 14 claims that
5 require specific effects on a patient's blood lipid levels.

6 First, Defendants will not induce infringement of the asserted claims that require a
7 particular minimum reduction in triglyceride levels, such as a 25% reduction, because
8 Defendants' "labels do not specifically encourage use of" their products to achieve the claimed
9 minimum reductions. *Grunenthal*, 919 F.3d at 1339. Defendants' ANDA products are generally
10 "indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe
11 (≥ 500 mg/dL) hypertriglyceridemia," and Amarin's clinical infringement expert agrees that they
12 are [REDACTED] Ex. 13 (Vascepa label) at 2;
13 Ex. 4 (Budoff Tr.) at 181:9-11. Reducing a patient's triglyceride levels, for example, by only 5%
14 (or by any amount less than the claimed amounts) is plainly within the scope of the indication
15 and an approved use of Defendants' ANDA products. Thus, as with the duration of treatment,
16 the labels are "indifferent" to the degree of reduction in triglycerides. At most, they merely
17 permit the claimed reduction, "but permission is different from encouragement." *Shire*, 2014
18 WL 2861430, at *5.

19 It is no answer to say that the "Clinical Studies" section of the labels reports a 27%
20 median reduction in triglycerides from baseline and a median 33% reduction relative to placebo
21 in a study involving 76 patients taking Vascepa. Ex. 13 (Vascepa label) at 7. As Amarin's
22 experts admit, those median numbers—i.e., the overall midpoints of the values reported for the
23 study's 76 patients—do not predict icosapent's effects in a real-world patient, or even in the
24 individual patients in the study, "which could be greater or less in an individual patient." Ex. 3
25 (Peck Tr.) at 154:6-14; *accord* Ex. 4 (Budoff Tr.) at 152:12-153:24. At most, they merely
26 "describe the infringing mode," which "is not the same as recommending, encouraging, or
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1 promoting an infringing use.” *Takeda*, 785 F.3d at 631 (citations, quotation marks, and
 2 alterations omitted).

3 Second, Defendants’ labels will not induce infringement of—i.e., specifically encourage
 4 practicing—those claims that require controlling LDL-C and Apo B levels, uses of icosapent that
 5 are not even approved by the FDA. The Federal Circuit has repeatedly held that “a method of
 6 use patent holder may not sue an ANDA applicant for induced infringement of its patent, if the
 7 ANDA applicant is not seeking FDA approval for the use claimed in the patent and if the use
 8 claimed in the patent is not FDA-approved.” *Allergan*, 324 F.3d at 1332; *accord Bayer*, 676
 9 F.3d at 1326 (“[T]he FDA has not approved [the patented] use and th[us] the defendants cannot
 10 be held liable for infringement of the patent.”); *AstraZeneca*, 669 F.3d at 1379 (“[A] patented
 11 method of using a drug can only be infringed under § 271(e)(2) by filing an ANDA that seeks
 12 approval to market the drug for that use.”); *Warner-Lambert*, 316 F.3d at 1354-55 (“[I]t is not an
 13 act of infringement to submit an ANDA for approval to market a drug for a use when neither the
 14 drug nor that use is covered by an existing patent, and the patent at issue is for a use not
 15 approved under the NDA.”).

16 As made clear in *Bayer*, a patent holder’s inability to sue ANDA applicants for
 17 unapproved uses includes potential uses described in the drug labeling. In *Bayer*, the method-of-
 18 use patent claimed to achieve three effects: a contraceptive effect, an anti-androgenic (anti-acne)
 19 effect, and an anti-aldosterone effect (reducing water retention). *Bayer*, 676 F.3d at 1319-1320.
 20 Bayer’s drug was only approved for oral contraception. *Id.* The Federal Circuit rejected Bayer’s
 21 arguments that the generic defendants’ labels encouraged the unapproved uses, even though the
 22 anti-androgenic and anti-aldosterone effects were presented in the Clinical Pharmacology and
 23 Pharmacodynamics sections of the drug label. *Id.* at 1322, 1325-26. As the Federal Circuit
 24 explained, “the fact that certain of the effects of a drug are described in the Clinical
 25 Pharmacology section of the label does not mean that the FDA has approved the use of the drug
 26 to produce those effects; it only ensures that physicians are aware of the full range of the drug’s
 27 pharmacological effects.” *Id.* at 1323.

1 The logic behind this uniform body of precedent is straightforward. Because the Patent
 2 Act limits liability under § 271(b) to one who “actively induces infringement,” it requires an
 3 element of scienter: “mere knowledge of possible infringement by others does not amount to
 4 inducement; specific intent and action to induce infringement must be proven.” *Warner-*
 5 *Lambert*, 316 F.3d at 1364. In a Hatch-Waxman case, these inquiries are “limited to an analysis
 6 of whether what the generic drug maker is requesting authorization for in the ANDA would be
 7 an act of infringement if performed.” *Id.* It follows that “the request to make and sell a drug
 8 labeled with a permissible (non-infringing) use cannot reasonably be interpreted as an act of
 9 infringement (induced or otherwise) with respect to a patent on an unapproved use, as the ANDA
 10 does not induce anyone to perform the unapproved acts required to infringe.” *Id.* at 1364-65.

11 That principle bars a finding of infringement for claims that require administering
 12 icosapent to reduce or not increase a patient’s LDL-C or Apo B levels. The FDA approved no
 13 such use of icosapent. It is “[t]he FDA-approved label for an approved drug [that] indicates
 14 whether the FDA has approved a particular method of use for that drug.” *Bayer*, 676 F.3d at
 15 1322. Here, the FDA-approved label for Vascepa indicates that the FDA has approved icosapent
 16 only to reduce triglycerides by some unspecified degree, without regard to a patient’s LDL-C or
 17 Apo B levels. As Amarin’s clinical infringement expert admits, [REDACTED]

18 [REDACTED] Ex. 4 (Budoff Tr.) at 180:22-24, 181:6-8.
 19 Those parameters are not even mentioned in the approved indication, or anywhere else in the
 20 “Indications and Usage” section of the label that must set forth the uses of the drug that the FDA
 21 has approved. 21 C.F.R. § 201.57(a)(6), (c)(2). In fact, [REDACTED]

22 [REDACTED]. Ex. 16 (FDA Complete
 23 Response Letter) at 1 ([REDACTED]
 24 [REDACTED]).

25 Again, Amarin cannot rely on the median results reported in the “Clinical Studies”
 26 section of the labels to avoid summary judgment. As a matter of law, “whether other effects may
 27 be described outside the Indications and Usage section of the FDA-approved label does not

1 address the issue” of induced infringement. *Bayer*, 676 F.3d at 1323. Under FDA regulations,
 2 only the “Indications and Usage section of the label” may set forth an indication; “indications or
 3 uses ‘must not be implied or suggested in other sections of the labeling if not included in this
 4 section.’” *Id.* at 1322-23 (quoting 21 C.F.R. § 201.57(c)(2)(iv)). Thus, “[t]he fact that certain of
 5 the effects of a drug are described in [other sections of] the . . . label does not mean that the FDA
 6 has approved the use of the drug to produce those effects.” *Id.* at 1323.

7 Likewise, it is immaterial that other parts of the labels describe “the drug’s
 8 pharmacological effects . . . when prescribing the drug for a purpose set forth in the Indications
 9 and Usage section.” *Id.* As the Federal Circuit made clear in *Bayer*, there is no inducement if
 10 the FDA has not approved the drug to produce the claimed effect, even if the drug “necessarily”
 11 produces that effect when taken as directed. *Id.* at 1321 (citing *Allergan*, 324 F.3d at 1324—
 12 “because those [claimed] uses were not approved by the FDA, the generic drug applicant could
 13 not be liable for infringement under section 271(e)(2)(A), even though [the drug] necessarily had
 14 those [claimed] effects in patients who took the drug for the approved purpose”).

15 It follows that “[t]he reference in the [‘Clinical Studies’] section of the label to the
 16 [effects on LDL-C and Apo B levels] of [icosapent] is certainly not a direct indication of an
 17 appropriate use for [Vascepa], and even if it could be considered an ‘implied or suggested’
 18 indication of an appropriate use, the [FDA] regulation expressly states that such implied or
 19 suggested uses do not constitute approved uses.” *Id.* at 1323. Nor can Amarin rely on expert
 20 “opinion [that] is contrary to the contents of the FDA-approved label.” *Id.* at 1325. Because
 21 Defendants “have submitted ANDAs seeking approval to market [icosapent] for uses that are not
 22 subject to [Amarin’s] method of use patents, [Amarin] does not state a claim for infringement”
 23 by inducement. *AstraZeneca*, 669 F.3d at 1380 (affirming dismissal of infringement claim).

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1 **2. Defendants cannot contribute to infringement of claims that require
2 specific effects on a patient's blood lipid levels because their products
3 are suitable to be used without achieving those effects.**

4 Amarin also cannot prove contributory infringement of the claims that require minimum
5 reductions in triglyceride levels or controlling LDL-C or Apo B levels.

6 The undisputed results of Amarin's MARINE clinical study on icosapent show that
7 Defendants' ANDA products are suitable for the noninfringing use of reducing triglycerides
8 without achieving the claimed effects. [REDACTED]

9 [REDACTED]
10 [REDACTED]
11 [REDACTED]

12 Amarin's experts confirm these results. As its clinical infringement expert concedes: (a)

13 in [REDACTED]
14 [REDACTED]; (b)

15 [REDACTED]
16 [REDACTED]

17 [REDACTED]; and (c) [REDACTED]
18 [REDACTED]

19 [REDACTED] Ex. 4 (Budoff Tr.) at 110:6-13, 248:11-23, 244:15-19. This
20 is more than enough to show that Defendants' ANDA products are not "especially made or
21 especially adapted for use in an infringement," but are instead "suitable for substantial
22 noninfringing use." 35 U.S.C. § 271(c).

23 Indeed, in cases where pharmaceutical patents require patients to have specific clinical
24 markers or effects, courts have found substantially lower rates of noninfringement sufficient to
25 defeat claims under § 271(c). *See Sanofi v. Glenmark Pharm. Inc., USA*, 204 F. Supp. 3d 665,
26 685 (D. Del. 2016) (finding "substantial non-infringing uses for Defendants' proposed ANDA
27 product" where it was "undisputed that approximately 20% of [the drug's] users do not have one
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1 of the claimed [markers]”); *In re Depomed*, 2016 WL 7163647, at *69, *aff’d sub nom.*
 2 *Grunenthal*, 919 F.3d 1333 (finding substantial noninfringing use where patentee’s expert
 3 provided “estimates of less than 5%”); *see also Sony*, 464 U.S. at 424, 444 (in copyright context,
 4 “7.3% of all Betamax use” was a “significant quantity” of noninfringing use).

5 **C. Amarin cannot prove indirect infringement of the four asserted claims that
 exclude concurrent lipid altering therapy.**

7 Defendants are also entitled at least to partial summary judgment on four of the 15
 8 asserted claims that exclude co-administration of icosapent with statins or other lipid-altering
 9 therapies. These four patent claims require that a physician administer icosapent to a patient
 10 “who does not receive concurrent lipid altering therapy” such as a statin. The Court has
 11 construed “concurrent lipid altering therapy” as “a medication to alter lipid levels in a subject
 12 whereby the medication is administered concurrently/concomitantly with the administration of a
 13 pharmaceutical composition comprising [icosapent].” D.I. 135 at 5-7. For the reasons discussed
 14 below, Amarin cannot prove indirect infringement of these claims.

15 **1. Defendants cannot induce infringement of claims that exclude the
 concurrent use of lipid-altering therapy because the labels do not
 encourage using icosapent without a lipid-altering therapy.**

18 Defendants’ “labels do not specifically encourage use of” their products by patients who
 19 are not receiving a concurrent lipid-altering therapy such as a statin. *Grunenthal*, 919 F.3d at
 20 1339. Nothing in Defendants’ labels instructs, encourages, recommends, or promotes the
 21 exclusion of a concurrent lipid-altering therapy. Rather than encourage against coadministration
 22 with a lipid-altering therapy, the labels state that “no drug-drug interactions were observed” upon
 23 coadministration with a statin, and that 25% of patients receiving Vascepa in Amarin’s MARINE
 24 study were on concomitant statin therapy. Ex 13 (Vascepa label) at 5-7. Even Amarin’s clinical
 25 infringement expert agrees that the labels are [REDACTED] and that there is not [REDACTED]

26 [REDACTED]
 27 [REDACTED] Ex. 4 (Budoff Tr.) at 172:3-11. Instead, as Amarin’s

1 FDA expert explains, Defendants' labeling teaches that a physician "should use his or her
 2 discretion with respect to use with a statin or without a statin." Ex. 3 (Peck Tr.) at 102:14-19;
 3 *see also* Ex. 4 (Budoff Tr.) at 173:11-15. As with the duration of treatment, the labels are
 4 "indifferent" to whether physicians administer icosapent with or without a concurrent lipid
 5 altering therapy. *Shire*, 2014 WL 2861430, at *5. At most, they permit the claimed exclusion of
 6 a concurrent lipid altering therapy, "but permission is different from encouragement." *Id.*

7 Moreover, Amarin cannot point to the "Clinical Studies" section of the labels to avoid
 8 summary judgment. That section of the labels state that "[t]wenty-five percent of patients were
 9 on concomitant statin therapy" in a clinical trial. Ex. 13 (Vascepa label) at 7. But this is
 10 immaterial to the inducement inquiry. That some patients were co-administered statins in a
 11 clinical trial and some were not does not prove that Defendants' labels specifically encourage a
 12 physician to administer icosapent to a patient who does not receive concurrent lipid altering
 13 therapy. At most, the Clinical Studies section is "[m]erely describing" that some patients were
 14 not on concomitant statin therapy, not specifically "suggesting that an infringing use should be
 15 performed." *Takeda*, 785 F.3d at 631 (quotation omitted). And the labels do not specify whether
 16 patients in that clinical study received any lipid-altering therapies apart from statins. *See id.* at 7.
 17 Even Amarin's clinical infringement expert admits that [REDACTED]
 18 [REDACTED]. Ex. 4
 19 (Budoff Tr.) at 173:25-174:8. Thus, Defendants cannot induce infringement of these patent
 20 claims as a matter of law.

21 **2. Defendants cannot contribute to the infringement of claims that
 22 exclude concurrent lipid-altering therapy because their products are
 23 suitable to be used with a lipid-altering therapy.**

24 Amarin also cannot prove contributory infringement of the claims that exclude a
 25 concurrent lipid-altering therapy. Amarin's own data confirms that Defendants' ANDA products
 26 are suitable for the noninfringing use of reducing triglycerides when used concurrently with a
 27 lipid-altering therapy. In the MARINE study described in the patents and in the Clinical Studies
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1 section of the labels, “twenty-five percent of patients were on concomitant statin therapy.”
2 Ex. 13 (Vascepa label) at 7; Ex. 12 (MARINE study report) at 69. As discussed, this is reported
3 in the product labeling. Ex. 13 (Vascepa label) at 6-7. In practice, it is even less common for
4 patients to receive Vascepa without concurrent statin therapy. Amarin’s clinical infringement
5 expert concedes that [REDACTED] and that further,
6 [REDACTED] Ex. 4 (Budoff Tr.) at
7 102:14-103:3; *see also id.* at 51:12-14. Using Defendants’ ANDA products with a concurrent
8 lipid-altering therapy such as a statin is “in accordance with the use for which the products[s]
9 [are] indicated.” *Grunenthal*, 919 F.3d at 1340. Thus, this suitable, non-infringing use defeats
10 Amarin’s claims of contributory infringement.

11 **IV. CONCLUSION**

12 The Court should grant summary judgment of noninfringement as to all asserted claims
13 in favor of Defendants.

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CERTIFICATE OF SERVICE

Pursuant to FRCP 5(b) I hereby certify that I am an employee of BROWNSTEIN HYATT FARBER SCHRECK, LLP, and on this 9th day of August, 2019, I served the document entitled, **DEFENDANTS' MOTION FOR SUMMARY JUDGMENT OF NONINFRINGEMENT**, on counsel of record through the CM/ECF system.

/s/ Jeff Tillison
Employee of Brownstein Hyatt Farber
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